

REMARKS

This Response addresses the Office Action mailed on May 25, 2004. Claims 5, 7-10, 15, 19, 21, 23 and 25-29 have been amended. New Claims 39-48 have been added. Also, as noted above, the Response filed on February 13, 2004 included two claims listed as Claim 35. In this Response, Applicant has canceled the second Claim 35 (now identified as Claim 35A), and replaced this claim with new Claim 40.

The amendments and New Claims 39-48 are supported by the specification. No new matter has been presented.

Claim Rejections – 35 U.S.C. § 102

Claims 2-5, 7-11, 14-17, 19, 21 and 23-38 have been rejected under 35 U.S.C. §102(e) as being anticipated by Harish et al. (U.S. Patent Application No. 2002/0122877 A1). Harish et al. is directed to a method of forming a polymeric coating on a stent. The Harish et al. method includes forming a polymeric sheath that may contain a drug, inserting a stent into the sheath, and then heat treating the sheath so that the sheath is converted into a polymeric coating disposed on the stent (see generally paragraphs 35, 40 and 41).

A. Claims 8, 19, 36-38 and 40

Harish et al. discloses that the composition for forming polymeric sheath 24 can contain a radiopaque element such as gold (see paragraph 34). As noted above, polymeric sheath 24 is converted to coating 26 by way of a heat treatment. Harish et al. also disclose that a second polymeric coating can be formed onto at least a portion of coating 26 (see paragraph 49). This second polymeric coating may or may not contain an active ingredient (i.e., a drug).

However, there is nothing in Harish et al. that discloses the precise coating structure of the present invention. In particular, Harish et al. clearly do not disclose a final coating for a medical device that includes: “(a) a **drug layer** containing a drug and a polymer; (b) a **topcoat layer** disposed over the drug layer, the topcoat layer free from any drugs; and (c) a **film-forming**

layer disposed over the topcoat layer, wherein a light- and/or UV-protective compound is included in the film-forming layer.” The prior art fails to disclose a coating configuration that includes three different layers each having a different function: (1) a first layer acting as a drug reservoir; (2) a topcoat or drug diffusion barrier layer that covers a part of the drug layer; and (3) a film-forming protective layer having a compound with the ability to reduce the amount of light that reaches the drug in the underlying layer. Without this exact coating structure, it can not be said that the prior art anticipates the present invention.

It is the Examiner's position, on the other hand, that Harish et al. anticipates the present invention because it discloses “a top coating material that has dispersed within it active agent and the UV-protective compound qualifies as an active compound.” This statement is not true on two fronts. First, Harish et al. only describe the radiopaque elements with respect to the composition for forming the polymeric sheath (which is later converted to the drug coating). There is nothing in Harish et al. (e.g., in paragraph 49) that suggests that the optional topcoat should have a radiopaque element. Also, there is no reason to believe that a UV-protective compound qualifies as an active agent within the ambit of the Harish et al. disclosure. Rather, radiopaque elements are only meant to assist the physician in directing and locating the stent during a procedure, and are not meant to have any medicinal qualities.

The Examiner previously found that Claims 8 and 19 should be allowable, but has since rejected these claims based on the Harish et al. disclosure. Applicant respectfully requests the Examiner to reconsider her position in light of the above remarks and allow the claims (including the dependent Claims 36-38 and 40).

B. Claims 2-5, 7, 9-17, 21 and 23-35

Harish et al. disclose that a radiopaque element can be included in a composition for a polymeric sheath. However, it does not disclose the precise mass ratios claimed by the present invention. For instance, with respect to Claims 5, 15 and 45, Harish et al. does not disclose

either explicitly or implicitly a coating that has a second layer where the mass ratio between the light- and/or UV-protective compound and the polymer in the second layer is between about 3:1 and about 1:3. Moreover, with respect to Claims 9, 26, 28 and 33, Harish et al. does not disclose a coating that has a layer containing a drug, a polymer and a light- and/or UV-protective compound where the mass ratio between the components is specifically between about 1:1:2 and about 1:3:20.

Instead, Harish et al. merely discloses that “[s]ufficient amounts of radiopaque elements or radioactive isotopes may be dispersed in the composition [for the polymeric sheath].” The “sufficient amounts” taught by Harish et al. are only with respect to the amounts necessary for allowing a physician to view the stent. Harish et al. provide no direction on how much of the radiopaque elements might be needed to protect underlying drug molecules from degradation caused by harmful radiation. So, Harish et al. not only fails to disclose any range of mass ratios that overlap the present invention, but it also fails to provide any hint or suggestion on the critical amount of radiopaque elements that would be needed to achieve the intended results of the present invention (i.e., protecting drugs from harmful light).

In the present Office Action, the Examiner has not even provided a hint as to where in the Harish et al. disclosure the mass ratios claimed in the present invention might be found. If the Examiner wishes to maintain the rejection, Applicant respectfully requests the Examiner to specifically point-out where in the reference such ratios are disclosed.

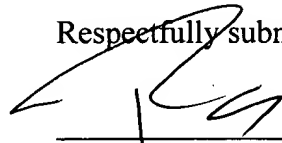
CONCLUSION

Claims 2-5, 7-11, 14-17, 19, 21 and 23-48 are pending in this application. Examination and allowance of the claims is respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned at (415) 954-0345.

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Respectfully submitted,



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